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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,315	04/30/1999	EUGENE S. PEARLMAN	108604/002	8170

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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/303,315

Applicant(s)

PEARLMAN, EUGENE S.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-17, 19-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 13-17, 19, 20 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 21, 23, 24, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 0705
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 25 April 2005, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 13-17, 19-21, and 23-27 are currently pending. Claims 5-11, 13-17, 19, 20 and 25 are withdrawn from consideration, as being drawn to non-elected species. Claims 12, 18, and 22 were cancelled.

After a careful review of the prosecution history, the Examiner would like to remind Applicant of the species Election set forth in the paper dated 15 December 2000. In the response dated 2 January 2001, Applicant elected the species "Hepatitis algorithm". An action on the merits of claims 1-4, 21, 23, 24, 26, and 27, as they read on the elected species, follows.

#### **Claim Objections**

Claim 24 has been amended to read "wherein m equals to one". This is grammatically awkward. Perhaps Applicant intends the claim to read "m equals one". Correction is requested.

Claim 4 recites "the method of claim 3" twice. This is redundant. Correction is requested.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, step (d), recites “not allowing a technician to add unnecessary tests”. It is admitted that a fully automated method and system does not require the intervention of a technician; however, there is no disclosure of specifically disallowing technician intervention. Furthermore, it is the **system** that eliminates unnecessary tests (see page 1, lines 5-7). Page 2, lines 20 –21 further state that “the **method** can select the next appropriate test to be carried out and eliminates the unnecessary tests”. Applicant does not point to support for the amended limitation. Neither the originally filed claims nor the specification teach or recite a method wherein a technician is “not allowed” to add tests, of any kind. There is no disclosure of preventing a technician from adding tests, therefore this limitation constitutes new matter.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 4 it is unclear whether Applicant is intending a step of modifying the diagnostic algorithm, or is intending a step of "implementing" a modified algorithm by "using" a modified computer architecture code. Clarification is requested.

Claim 4 still recites "to implement any modifications ". It is unclear whether or not this is intended to be an active positive step of "optimally modifying the diagnostic algorithm" or not. Clarification is requested.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 21, 23, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (US 6,099,469; PTO Form 892 cited 13 March 2001), in view of Adlassnig et al. (Artificial Intelligence in Medicine (1995) Vol. 7, pages 1-24; PTO Form 892 cited 8 March 2002).

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Armstrong et al. teach a reflex algorithm for assessing patients (in this case, cardiac patients), which does not require human decision-making in selecting assays to be performed (abstract). In regard to claim 1, Armstrong et al. teach a reflexive disease specific algorithm for use in a computer-assisted method, which analyzes what clinical tests should be performed. A first test is performed on the sample, then, based upon the result of that test in comparison with preset guidelines, a second test is run. This process is repeated until an endpoint is reached. That endpoint is a diagnosis of a condition (columns 4-11 specifically describe the tests, etc.). Figures 1B- 1F set forth the decision tree of clinical tests and diagnoses used in the particular algorithm for the disease state. Figure 2, and the discussion from column 11:line 30 to column 14: line 25, set forth various systems and apparatus for performing the method. The reflex algorithm of the present invention, by selecting subsequent tests based upon the results of previously run assays, automatically selects the appropriate biochemical markers for a given clinical situation, which concomitantly eliminates the need for human decision making in selecting tests, and minimizes the number of necessary tests that have to be run (column 4, lines 1-10). Therefore, the method and system is capable of omitting the execution of unnecessary assays while ensuring that all necessary combinations of laboratory results are covered.

In regard to claim 2, Armstrong et al. teach running more than one test (columns 5, lines 56-67).

In regard to claims 3 and 4, computer program code is utilized to implement the method (column 11, line 31 to column 12, line 45).

In regard to claims 21, 23, and 24, "the algorithm can be implemented on a computer" (abstract). The system contains a memory, as required by step (a) of claim 21 (see Figure 2).

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The system contains a means of selecting tests necessary to diagnose a suspected disease from tests ordered by a physician (column 5, lines 13-19). In addition, the system can read out tests from memory, wherein tests comprise more than one test or at least one test, as in claims 23 and 24 (column 12, lines 46-67 to column 13, lines 1-11). Finally the system outputs a diagnosis, based upon the clinical tests performed (column 15, line 45).

Armstrong et al. do not teach that their automated diagnostic platform uses a Hepatitis algorithm, as in claim 26. However, Adlassnig et al. teach a Hepatitis algorithm for use with a method to diagnose Hepatitis A and B with an expert system (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have utilized the algorithm for Hepatitis of Adlassnig in the method and system of Armstrong. The motivation to do so is set forth by Adlassnig at page 2, who states the need for an automated system to perform automated analysis tests for Hepatitis while maintaining the physician's role as the "final" decision maker.

### **Conclusion**

Claim 27 is free of the prior art, but is rejected as being dependent from claim 1, which recites new matter. Claim 1-4, 21, 23, 24, 26, and 27 are rejected.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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July 21, 2005  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
7/21/05